

Applicants: Montgomery *et al.*
Filing Date: April 21, 2000
Serial No.: 09/552,994
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Applicants have added new claim 56 directed to an embodiment of the composition of claim 1 having less than about 40 % monomers. Support for new claim 56 may be found, for example, at page 14, lines 10-11. No new matter is added in new claim 56.

Applicants have added new claim 57 directed to a method of making a composition. Support for new claim 56 may be found throughout the application; see, for example, page 10 lines 1-2, 13-14, and 17-20; page 11 lines 5-9; page 13, lines to page 14, line 4; page 15, line 1, to page 16, line 4; page 16, line 5, to page 18, line 9, as well as the examples of the application. No new matter is added in new claim 57.

Applicants have added new claims 58 and 59 directed to embodiments of new claim 57. Support for new claim 58 and new claim 59 may be found in the application; see, for example, page 14 lines 10 to 17. No new matter is added in new claims 58 and 59.

Rejections Under 35 USC § 112, Second Paragraph: Trademark Use

The Examiner objected to claims 7, 43, 52-55 for containing the trademark names MLU-340, MLU-341, and MLU-342. Claims 7, 43, 52, and 55 were modified by deleting the trademark name, and adding the name of the compound, "dimethacrylate polyetherurethane oligomers," to which they refer. Because claims 53 and 54 depend from claim 52, Applicants submit that the amendment of claim 52 moots the Examiner's objections to claims 53 and 54.

Rejections Under 35 USC § 112, Second Paragraph: Indefiniteness

The Examiner rejects claims 7-9, 19-21 and 32-55 under 35 U.S.C. §112, second paragraph, as indefinite.

The Examiner asserts that claim 7 contained terms not recognized in the art. Although Applicants contend that the asserted terms are known to one of ordinary skill in the art, Applicants have amended claim 7 to address the Examiner's concerns as to the use of

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MLU-340, -341, and -342. Applicants respectfully submit that this amendment moots the Examiner's rejection.

The Examiner asserts that the term "molecular weight" as used in claims 8 and 9 is unqualified for not stating the "type" of molecular weight: "number average or weight average." Applicants respectfully disagree with the Examiner and contend that the term "molecular weight" is well known in the art and sufficiently clear and definite to one of ordinary skill in the art. Applicants do not comprehend the Examiner's basis for rejection and thus respectfully request clarification.

The Examiner asserts that the term "bioadhesion synergist" as used in claims 19-21 is not art recognized and is unclear. Applicants respectfully disagree and refer Examiner to pages 21-23 of the specification, in particular page 21, wherein "bioadhesion synergist" is defined as a compound or compounds that increases the bioadhesive strength of the inventive composition when used in conjunction with adhesion promoters. In light of the specification, including the passages referenced above, Applicants submit that the term "bioadhesion synergist" is sufficiently clear and definite to one of ordinary skill in the art.

The Examiner asserts that claim 32 is unclear since "a composition is a mixture of materials, it is unclear how mixture can be in different parts." Although Applicants submit that the language of claim 32 was clear in light of the specification, Applicants have amended claim 32 in order to address the Examiner's concern. Claim 32 now sets forth a two part system. Applicants respectfully submit that the amended language of the claims overcomes the Examiner's rejection. Applicants submit that this is also true for the Examiner's rejections of claim 33, which depends from claim 32.

Applicants further submit that the Examiner's rejections of claims 34-55 are overcome by the above arguments. To the extent that the Examiner sustains any rejections under 35 U.S.C. §112 for claims 34-55 under 35 U.S.C. §112 in light of the arguments above, Applicants respectfully request clarification of any remaining objections.

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Rejections Under 35 USC § 103(a)

The Examiner contends that claims 1-51 are unpatentable under 35 USC 103(a) over Jensen et al. (US Patent No. 6,086,370) in view of Yamamoto et al. (US Patent No. 5,530,038), Della Valle et al. (US Patent No. 5,876,744), Cordes et al. (US Patent No. 6,153,216), Kumar et al. (US Patent No. 5,006,571), Peppas et al. (Biomaterials 17, 1996, 1553-1561) and Kanerva, et al. (Contact Dermatitis 33, 1995, 84-89).

The Examiner asserts that Jensen et al. describes a composition that contains "polymer strength reducers" intended to reduce the amount of heat that the patient experiences, "tissue adherence accentuators" and materials such as "titanium dioxide and silicon dioxide" that the Examiner equates to Applicant's "light attenuating pigment." The Examiner contends that the Jensen et al. patent also discloses a low exothermic composition and that therefore said invention should be rejected on the basis of obviousness under 35 USC 103(a). The Examiner concedes, however, that Jensen et al. does not disclose any of the following: a two part composition as in claim 32 of the present invention, ethyl-4-dimethylaminobenzoate as a curing agent synergist, the addition of a bioadhesion synergist, nor the urethane dimethacrylates of claim 43 of the present invention.

Applicants disagree with the Examiner's position. Applicants submit that Jensen et al. does not disclose, teach, or suggest employing compositions comprising curable unsaturated compounds as described by the present invention. Each of the compositions of Jensen et al. include additives such as reflective materials to lower excess heat released during polymerization (see column 14, lines 41-42; column 16 lines 31-33, and column 17, lines 4-7).

Applicants submit that the present invention is fundamentally distinct from the composition described in the Jensen et al. disclosure. First, although Jensen et al. addresses exothermic phenomena, the reduction in exothermic effects disclosed by Jensen et al. is through additive agents or diluents referred to as "polymerization strength reducers," such as oils, mineral oils, certain disclosed alcohols, and certain disclosed polyols (column 8, lines 20-32), or other additives referred to as "reflective materials" that include certain disclosed inorganic materials (column 9, lines 15-43). None of the materials disclosed in Jensen et al. for use in reducing exothermic phenomena are in and of themselves curable. By contrast, the present invention teaches judicious selection of *curable unsaturated compounds that comprise a curable composition as a means of reducing peak exotherms*. Thus, the present invention is distinct from the disclosure of Jensen et al., whether considered alone or in light of any of the other references cited by the Examiner, in that reduction in peak exotherms are achieved through use of carefully selected *curable* compounds based upon their unsaturation indices. Jensen et al. discloses no such composition or method. Further, unlike the present invention, Jensen et al. is silent on the quantification of asserted reductions in exothermic phenomena employing the approach described therein. In support, Applicants respectfully direct the Examiner to page 13 line 15 to 25 of the present application, where "curable unsaturated compounds" are defined. Applicants respectfully submit that "curable unsaturated compounds," as used in the claims, do not include non-curable diluents. Applicants respectfully direct the Examiner to page 18 line 10 to page 20 line 5. As an inspection of the cited passage of the present application reveals, non-curable diluents in the present invention are employed to reduce viscosity. ~~They are not included in the definition of "curable unsaturated compounds."~~

The present invention achieves peak exotherm reduction manipulating the chemical characteristics of the polymerizing moieties that comprise the barrier composition themselves. On this subject, Jensen et al. is silent. The present invention describes the surprising discovery that, by judiciously selecting curable unsaturated compounds of desirable unsaturation index, the heat generated or released during curing can be reduced thus resulting in a quantifiable low peak exotherm. No such method or composition is disclosed or even suggested by Jensen et al. Further, the present invention quantifies the peak exotherms

achievable employing the compositions and methods of the invention, with fully enabled, preferred embodiments that result in peak exotherms of less than or equal to 50 °C (120 °F), 43.4 °C (110 °F) and 40 °C (104 °F). In contrast, the assertions of Jensen *et al.*, employing only certain diluents and inorganic materials to reduce peak exotherms, are unsupported and undefined with regard to quantification of reductions in peak exotherms.

The present invention describes a composition comprising less than about 40%, most preferably less than about 5%, and even comprising zero concentration of monomers. The present invention also specifically discloses the preferable use of monomers with a molecular weight greater than or equal to 1000 due to the sensitizing and undesirable taste attributes of lower molecular weight monomers. Although Jensen *et al.* recognizes that monomer content is responsible for exothermic effects, Jensen *et al.* does not address either monomer use or monomer molecular weight and instead is directed to compositions different from those taught in the present invention, instead containing various specified diluents.

Although the Examiner concedes that Jensen *et al.* does not address methods or compositions aimed at lowering peak exotherms, the Examiner asserts that the claims of the present invention are rendered obvious because Jensen *et al.* discloses that the compositions therein did not cause human discomfort due to heating. In order to avoid confusion with Jensen *et al.*, Applicants tested the material disclosed in Jensen *et al.*, available under the trademark OpalDam, according to the same procedures as the present invention (see Example II, pages 25-29 in the present application). ~~The results of the testing are disclosed in the present application, and clearly distinguishes the present invention from that disclosed in the Jensen *et al.* reference.~~ The peak exotherm value of the material disclosed in Jensen *et al.* exceeded the peak exotherm value of the present invention (see Example II, page 26 and Table 3, page 28). Thus, the present invention is distinguishable from the Jensen *et al.* disclosure on the very issue upon which the Examiner bases his rejection—the exothermal characteristic. Moreover, after curing, the Jensen *et al.* material yielded a “brittle solid that did not possess the flexural properties” of the present invention. Indeed, this distinguishable brittle solid property—absent from the present invention—is an express aim of the Jensen *et al.* disclosure (see, for example, column 4, lines 32-38, Jensen *et al.*). Thus, using the

polymer strength reducers, tissue adherence accentuators, light attenuating pigments, and/or the photoinitiators of Jensen *et al.* (1) does not yield the same composition as the methods of the present invention, and (2) yields peak exotherms in significant excess of the present invention. Moreover, Jensen does not disclose, teach, or suggest the use of curable unsaturated compounds of specified unsaturation index for compositions having a low peak exotherm of less than about 50 °C, as taught in the present invention, in the absence of reflective materials. Further, Jensen *et al.* is bereft of any suggestion, alone or in combination with the other art cited by the Examiner, to devise compositions of oligomers with low monomer content to achieve peak exotherms of less than about 50 °C. Applicants submit that claims 1 (and dependent claims 2-31) and 37 (and dependent claims 38-51) are not obvious in light of Jensen for the reasons cited above. Further, Jensen *et al.* does not disclose, teach, or suggest two-part compositions of unsaturated curable compounds having peak exotherms less than about 50 °C and lacking reflective materials, as in claim 32 (and dependent claim 33) of the present invention.

The Examiner asserts that Yamamoto *et al.* discloses an adhesive composition that may contain a combination of camphorquinone and diethylaminobenzoic acid when room temperature curing is desired, that may be in the form of a two-part kit. The Examiner asserts that, because Yamamoto *et al.* lists camphorquinone and diethylaminobenzoate as a curing agent and synergist combination for use on tooth surfaces, and that such combination may be used at room temperature and that the present invention discloses adhesion by curing at room temperature, the present invention should be rejected under USC 103(a) as being obvious over Yamamoto *et al.* However, Applicants submit that the present invention pertains to a composition that can be placed in contact with mucosal or other skin surfaces, as opposed to the Yamamoto *et al.* disclosure, which is directed to compositions and methods of bonding material (certain disclosed composite resins) to dentin/tooth surfaces without the necessity of etching. The present invention is described in embodiments of an oral mucosal barrier placed on gingival tissue—not tooth or dentin-containing tissue—and curing *in situ* to provide a physical barrier against contact of the gingival tissue. Yamamoto *et al.*, in contrast, discloses a composition applied to tooth surfaces—not mucosal or gingival surfaces—that acts synonymously to acid-etching, a process in which enamel and dentin are first decalcified by simultaneously applying phosphoric acid or citric acid

to the surfaces of enamel and dentin. Thus, the Yamamoto *et al.* disclosure starkly contrasts with the present invention: the present invention is applied to mucosal and other skin tissues in an application meant to *protect* the tissue from contact with the agents disclosed in the Yamamoto *et al.* disclosure—and so clearly the degree of sensitization considered in the two inventions differs. Indeed, anyone of ordinary skill in the art would realize that it would be wholly inadvisable to apply the materials disclosed in Yamamoto *et al.* to a mucosal, gingival, or other innervated soft tissue for any length of time. Applicants respectfully submit that the disclosure of Yamamoto *et al.* is inapplicable, because it is directed to compositions that are meant to ***remain on a tooth indefinitely***, whereas the present invention involves compositions that are meant to be in contact with tissue ***temporarily***.

Nowhere in Yamamoto *et al.* are camphorquinone and diethylaminobenzoic acid together disclosed as a particularly useful combination, but instead are disclosed in separate long lists of components that may or may not be employed together. Applicants respectfully argue that given the distinct applications of the Yamamoto *et al.* disclosure and the present invention that it was not obvious at the time of the present invention—or the Yamamoto *et al.* disclosure—to combine camphorquinone and diethylaminobenzoic acid to create a compound that can be applied to sensitive mucosal or gingival tissue. A person of ordinary skill in the art would not take from Yamamoto *et al.*'s disclosed dentin adhesives the suggestion to apply individual components comprising such adhesives to soft tissues, even assuming for the purposes of argument that camphorquinone and diethylaminobenzoic acid were disclosed as a useful combination. ~~The Yamamoto *et al.* disclosure is directed to adhesive compositions~~ that replace compositions requiring tooth etching. Yamamoto *et al.* does not teach, disclose, or suggest the use of camphorquinone and diethylaminobenzoate, either together or apart, with a curable unsaturated compound, or such a combination wherein such a combination exhibits a specific peak exotherm value. A person of ordinary skill in the art would not realize that such compositions or individual components of such compositions would be useful in different compositions for application to soft, innervated tissues. Indeed, Applicants contend that a person of ordinary skill in the art would find it surprising that compositions that adhere to dentin without the requirement of pre-etching the dentin might have components that can be employed on soft tissues without damage. In particular, Yamamoto

et al. does not render claim 1 (and dependent claims 2-31) and 37 (and dependent claims 38-51) obvious for the reasons cited above. Yamamoto does not render claims 32 and 33 obvious, merely because the composite resins disclosed therein may also be stored individually and combined, because the compositions of Yamamoto et al. differ strikingly in their use and properties with the compositions of the present invention. Yamamoto et al. does not disclose, teach, or suggest two-part systems for flexible bioadhesives. Yamamoto et al. does not render claims 34-36 obvious, for the reasons stated above and because the resins of Yamamoto et al. are not flexible. Yamamoto et al. does not render claim 43 (and dependent claims 44 and 45) obvious because Yamamoto et al. does not disclose, teach, or suggest curable unsaturated compositions comprising oligomers wherein the composition displays a peak exotherm of less than about 50 °C. Yamamoto et al. does not render claims 52-55 obvious because Yamamoto et al. does not disclose, teach or suggest compositions comprised of oligomers. Thus, Applicants submit that the Yamamoto et al. disclosure—either alone or in combination with Jensen et al. or any other cited reference—does not render any of the claims of the present invention obvious.

The Examiner asserts that Della Valle et al. discloses a composition having high bioadhesion and including polyethylene glycols and Polycarbophil. The Examiner asserts that because Polycarbophil is disclosed by Della Valle et al. as a highly bioadhesive polymer, the claims of the present invention should be rejected for obviousness under USC § 103(a). However, Applicants submit that Della Valle et al. discloses the use of bioadhesives in applications-addressing-rehydration.compositions useful for treatment of dried tissues. The rehydration compositions disclosed in Della Valle et al. are distinct in composition, manufacture, method of use, and application from the compositions of the claims of the present invention. Applicants contend that merely because the compositions of Della Valle et al. and the present invention can employ a common ingredient, the present invention should not be rendered obvious over Della Valle et al. The present invention is directed to compositions of low peak exotherms, some embodiments of which can also contain Polycarbophil and some embodiments that may contain other adhesives. Polycarbophil can be employed in the present invention in one or more embodiments, and is mentioned in claims 15 and 16 as one of many adhesion promoters. Della Valle et al. does not teach,

suggest, or disclose the use of Polycarbophil—or any other adhesion promoter—with a curable unsaturated compound having a peak exotherm of less than about 50 °C, or such a combination wherein the combination exhibits any specific peak exotherm value, or indeed any information as to the effect on peak exotherms of Polycarbophil, or its compatibility with in the compositions taught by the present invention. Indeed, Della Valle et al. does not disclose, teach, or suggest the combination of claim 1 (and claims 2-31), the two-part system of claims 33 and 32, the method of forming a flexible bioadhesive of specified peak exotherm of claims 34-36, the composition of claim 37 (and claims 38-51) of specified peak exotherm, nor the specific composition of claim 52 (and claims 53-55). The Della Valle et al. disclosure, directed at rehydration compositions, does not render any of the claims of the present invention obvious merely because the present invention may also employ Polycarbophil.

The Examiner asserts that Kanerva et al. discloses the concept that urethane dimethacrylates have very low irritative effects, pointing to Table 4 of that reference. Kanerva et al. is directed to studies on the *allergic* effects of (meth)acrylates in humans as measured by patch tests, as opposed to curable unsaturated compositions of low peak exotherm that may contain (meth)acrylates and methods of using them. Applicants submit that the Kanerva et al. disclosure, which does not disclose, teach, or suggest the curable unsaturated compounds of the present invention, or any of its methods, cannot render any of the claims of the present invention obvious, either alone or in combination with any of the other references cited by the Examiner.

The Examiner, along the same lines, asserts that Peppas et al. discloses that urethane dimethacrylates have very low irritative effects and thus render the claims of the present invention obvious. Peppas et al. is directed to the physical characteristics of certain bioadhesive materials, particularly in relation to tensile strength and the ease with which such materials may be separated from certain specified animal tissues like rabbit gastric mucosa (see, for example, the first full paragraph on page 1555 of Peppas et al.). Applicants submit that Peppas does not disclose, teach, or suggest the curable compositions having a peak exotherm of less than about 50 °C claimed in the present invention, nor the methods claimed

by the present invention. Thus, Applicants submit that Peppas *et al.*, either alone or in combination with any of the other references cited by the Examiner, does not render the present claims obvious.

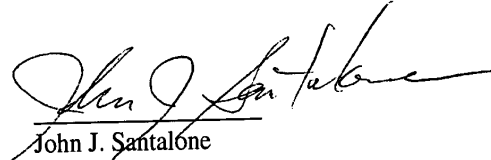
The Examiner asserts that Cordes *et al.* and Kumar *et al.* both disclose that divalent salts such as calcium or trivalent salts may be added to adhesive formulations containing carboxylated materials and that the addition of salts may increase adhesiveness, and asserts that this renders the claims of the present invention obvious under 35 USC § 103(a). Kumar *et al.* discloses the use of certain salts in adjusting the cohesivity of a denture adhesive composition comprising certain mixed salts, a copolymer, and the sodium salt of carboxymethylcellulose. Cordes *et al.* discloses certain adhesives useful in transdermal hormonal delivery patches, employing aluminum acetyl acetate (column 4, lines 33-37) to improve adhesive properties. Neither reference discloses, teaches, or suggests the use of adhesion promoters in combination with any polymerizable compositions with reference to its effects on peak exotherms, or in combination with compositions containing oligomers of specified molecular weight ranges or compounds of specific unsaturation indices. Further, neither Kumar *et al.* nor Cordes *et al.* provide any suggestion or motivation to combine the use of adhesives or adhesion promoters with curable unsaturated compounds of peak exotherms of less than about 50 °C, nor suggestions for methods combining such elements. Thus, Applicants submit that none of the claims of the present invention can be rendered obvious in light of either or both the Kumar *et al.* and Cordes *et al.* disclosures—alone or in combination with any of the other references cited by the Examiner.

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Conclusion

In light of Applicants' amendments and remarks, Applicants respectfully submit that this application is in condition for further examination or allowance. If there are any questions or comments relating to the present application, the Examiner is respectfully invited to contact Applicants' attorney at the telephone number below. No fee other than the fee for the three-month extension of time is believed to be necessary. If any additional fee is required, or overpayment has been made, please charge, or credit, our Deposit Account No. 11-0171 for such sum.

Respectfully submitted,



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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Montgomery *et al.*

Examiner: J. Mullis

Filing Date: April 21, 2000

Group Art Unit: 1711

Serial No.: 09/552,994

Docket: 13045

For: Low Peak Exotherm Curable Compositions

Kalow & Springut LLP
488 Madison Avenue
New York, New York 10022

November 2, 2001

Assistant Commissioner for Patents
Washington, D.C. 20231

**MARK UP OF AMENDMENTS IN
ACCORDANCE WITH 37 CFR 1.121**

1. (Amended) A composition, comprising:
- a [curable unsaturated] compound having an unsaturation index of at least about 500;
 - a curing agent; and
 - an adhesion promoter,
- wherein the composition is curable and has a peak exotherm of less than about 50 C.(120 F).
-

7. (Amended) A composition according to claim 6, wherein the dimethacrylate oligomer is [selected from the group consisting of MLU-340, MLU-341 and MLU-342] a dimethacrylate polyetherurethane oligomer.

Certificate of Mailing Under 37 C.F.R. 1.8

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Assistant Commissioner for Patents, Washington, D.C.

Date: 11-2-01 Name: J. Colwell

32. (Amended) A two part [composition] system[,] comprising:

a) a first part [comprising] which comprises a curing agent; and

[a curable unsaturated compound, an adhesion promoter and a curing agent, and]

b) a second part [comprising] which comprises a curing agent synergist of the curing agent of the first part,

[a curable unsaturated compound, and a curing agent synergist of the curing agent of the first part, wherein upon mixing of the first part and the second part curing takes place with a peak exotherm of less than about 50 C (120 F).]

wherein the first part or the second part or both further comprises a compound having an unsaturation index of at least 500 and an adhesion promoter and wherein upon mixing of the first part and the second part, curing is achieved with a peak exotherm of less than about 50 C (120 F).

43. (Amended) A composition according to claim 42, wherein the dimethacrylate oligomer is [selected from the group consisting of MLU-340, MLU-341 and MLU-342] a dimethacrylate polyetherurethane oligomer.

52. (Amended) A composition comprising a methacrylated polyetherurethane oligomer [(MLU-340)], capric/caprylic triglyceride, polycarbophil, camphorquinone, and ethyl-4-dimethylaminobenzoate.

55. (Amended) A composition according to claim 52, wherein the composition comprises a methacrylated polyetherurethane oligomer [(MLU-340)] in an amount from about 25 percent to about 98 percent by weight based on the total weight of the composition, capric/caprylic triglyceride in an amount from about 2 percent to about 50 percent by weight based on the total weight of the composition, polycarbophil in an amount from about 10 percent to about 50 percent by weight based on the total weight of

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the composition, camphorquinone in an amount from about 0.05 percent to about 0.30 percent by weight based on the total weight of the composition, and ethyl-4-dimethylaminobenzoate in an amount from about 0.1 percent to about 1.0 percent by weight based on the total weight of the composition.